

Rational Pharmaceutical Management Plus
Technical Assistance to the National Tuberculosis Control Program
Romania: Trip Report

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About RPM Plus

The Rational Pharmaceutical Management Plus (RPM Plus) Program, funded by the U.S. Agency for International Development (cooperative agreement HRN-A-00-00-00016-00), works in more than 20 developing countries to provide technical assistance to strengthen drug and health commodity management systems. The program offers technical guidance and assists in strategy development and program implementation both in improving the availability of health commodities—pharmaceuticals, vaccines, supplies, and basic medical equipment—of assured quality for maternal and child health, HIV/AIDS, infectious diseases, and family planning and in promoting the appropriate use of health commodities in the public and private sectors.

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Abstract

Tuberculosis is a growing health issue in Eastern Europe, and an inexpensive and effective treatment regimen exists promulgated by the WHO. USAID is funding the Rational Pharmaceutical Management Plus (RPM Plus) Program to strengthen the drug management aspects of national tuberculosis programs. In Romania, RPM Plus assessed drug management information needs for program managers and other key stakeholders of the Romanian national tuberculosis control program (NTP). Subsequent technical assistance has aimed to improve data collection and information use for the drug management component of the NTP. Following the inception of the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) Project in Romania, RPM Plus has complemented the GFATM Project activities with in 2004, the NTP holding a series of regional workshops with RPM Plus support on drug management issues for judet TB physicians and coordinators, pharmacists and HIH representatives, during which key issues of ordering and stocking were discussed and a survey of training needs completed. MSH will collaborate with the NTP using GFATM Project funding on the production of a drug management guide which will be the basis of subsequent a training programme.

Recommended Citation

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Key Words

Tuberculosis, national tuberculosis program, tuberculosis drugs, drug management information system, training, Romania.

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ACRONYMS

DMIS	drug management information system
E&E	Bureau for Europe and Eurasia [USAID]
GFATM	The Global Fund to Fight AIDS, Tuberculosis & Malaria
GLC	Green Light Committee
MDR-TB	multi-drug resistant tuberculosis
MoH	Ministry of Health
MSH	Management Sciences for Health
NHIH	National Health Insurance House
NIP "Marius Nasta"	National Institute of Pneumology "Marius Nasta"
NIRDH	National Institute of Research and Development in Health
NTP	national tuberculosis program
RPM Plus	Rational Pharmaceutical Management Plus Program [MSH]
TB	tuberculosis
USAID	United States Agency for International Development
WHO	World Health Organization

BACKGROUND

RPM Plus and in-country partners, the Ministry of Health (MOH), National Tuberculosis Control Program (NTP) and the National Health Insurance House (NHIH), are strengthening the drug management information system (DMIS) for the NTP. A steering group, meeting in November, 2003 began to prioritize the identified DMIS needs and plan specific activities to integrate data collection, analysis and use for drug management.

Subsequently in the first half of 2004, the NTP organized a series of one day regional meetings for TB program staff from each judet (county) to review and discuss drug management and reporting. These meetings have been held to develop a common understanding of the issues facing the TB DMIS, to inform about current procedures and to improve ordering practices at the judet level. RPM Plus supported the first of the regional meetings and has worked with the NTP to collect data on drug management and staff training needs through a survey of participants.

In November 2003, RPM Plus and the National Institute for Research and Development in Health (NIRDH) signed an agreement whereby the NIRDH would act as a technical and logistical partner on RPM Plus activities in Romania, to facilitate continued progress of RPM Plus work in between technical assistance visits. Planned activities with the NIRDH include developing the capacity of NIRDH personnel to provide TA on TB drug management issues.

Purpose of Trip

RPM Plus will work with RPM Plus partner, NIRDH, to finalize the implementation of the next steps of the RPM Plus work plan (training of trainers workshop, drug management training for judet level TB staff) and collaborate with the NTP in the development of a drug management guide for judet TB managers and pharmacists, and monitor implementation of the sub-contract with NIRDH.

Scope of Work

- Provide briefing and/or debriefing to the USAID Mission, as requested;
- Prepare a TOT workshop (schedule event, participants list, venue, trainers, etc) to build capacity of NIRDH and NTP staff and local pharmacists to train judet level staff in basic drug management;
- Plan with the NTP, training for TB staff, NHIH representatives and pharmacists from judets in DMIS and DM practice.
- Finalize, under the procurement rules established for the GFATM grant, an agreement for MSH to collaborate on the drafting of a DM Guide with the NTP.
- Further discuss timing and implementation of work plan activities relating to pharmaceutical management for MDR-TB treatment with the NTP, in light of the Romanian application to the Green Light Committee (GLC).

The full text of the Request for Country Clearance can be found in Annex 1 and a list of persons met during the visit appears in Annex 2.

ACTIVITIES

1. Prepare a TOT workshop (schedule event, participants list, venue, trainers, etc) to build capacity of NIRDH and NTP staff and local pharmacists to train judet level staff in basic drug management.

(See under next paragraph)

2. Plan with the NTP, training for TB staff, NHIH representatives and pharmacists from judets in DMIS and DM practice.

RPM Plus had been collaborating with the National Tuberculosis Control Program since 2002, in particular working on activities to strengthen pharmaceutical management to ensure the availability of low-cost, high-quality 1st-line anti-TB drugs to health facilities and TB patients. RPM Plus's work plan includes a training activity to build up capacity of judet-level staff in drug management. Recognizing this history of support, the NTP/Program Implementation Unit of the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) project proposed to award a single-source contract to MSH, to provide technical input into the development of a Drug Management Guide aimed at judet-level TB program staff.

These activities, developed from earlier RPM Plus activities and representing a minor change in emphasis to the RPM Plus work plan, were discussed with Dr. Cristi Popa, Dr. Iuliana Husar, and Ms. Ioana Novac, but in the context of the GFATM project that they are now implementing at the NIP.

It was recognized that the proposed Drug Management Guide would be a key resource and foundation for the training course. Therefore the timing and the preparation for the training course could only be finalized as the Guide reached completion. However RPM Plus and counterparts were able to lay the groundwork for the Training of Trainers and training of TB staff activities by establishing the number and kind of person who would attend the TOT course (10-12 from the Institutes of Pneumology and Pharmacy, NIRDH, and pharmacy schools); the benefits of conducting the first regional training after the TOT, so that trainers could immediately put the theory into practice; and possibly scheduling (November/December 2004).

3. Finalize, under the procurement rules established for the GFATM grant, an agreement for MSH to collaborate on the drafting of a DM Guide with the NTP.

Discussions took place on a number of issues: the acceptability of single-source contractual arrangements to the Principle Recipient, defining the scope of work, and administrative issues. A draft scope of work (annex 3) was prepared. This would be used by MSH to prepare a budget for submission to the Program Implementation Unit (PIU) of the GFATM Project. It was agreed to exchange sample contracts in order to facilitate the completion of a mutually acceptable contract.

4. Further discuss timing and implementation of work plan activities relating to pharmaceutical management for MDR-TB treatment with the NTP, in light of the Romanian application to the Green Light Committee.

RPM Plus met with Dr. Cristi Popa and Ms. Ioana Novac to discuss the implementation of proposed MDR-TB activities. The NTP is supportive of the training course in pharmaceutical management for MDR-TB treatment which is planned to be held jointly with counterparts from the Moldovan NTP and MOH, in Romania. Suitable dates after the summer vacation period would be explored.

5. Provide briefing and/or debriefing to the USAID Mission, as requested;

RPM Plus debriefed Dr. Gabriela Paleru, USAID Senior Health Specialist, on the activities undertaken during the trip, progress on the work plan and the new development of the possible contract between the PIU and MSH (funded by the GFATM project) for technical input to the development of the drug management guide.

Collaborators and Partners

Professor Ioan Paul Stoicescu, General Director, National Institute of Pneumology "Marius Nasta" and Manager, National Tuberculosis Control Programme

Dr. Iuliana Husar, Coordinator, GFATM TB Program, National Institute of Pneumology "Marius Nasta"/ Program Implementation Unit

Dr. Cristi Popa, National Institute of Pneumology "Marius Nasta"

Ms. Ioana Novac, Project Assistant, Program Implementation Unit

Dr. Cassandra Butu, Chief of the Training and Consultancy Department, National Institute for Research and Development in Health

Adjustments to Planned Activities and/or Additional Activities

During the previous TDY to Romania (February 2004) RPM Plus had agreed to, in the first instance, work with the NTP on the development of the Drug Management Guide by commenting on a draft list of contents. Subsequently an exchange of ideas led to a revised contents list which the NTP placed discussion of on the agenda of a meeting they convened on July 9th, 2004. The invitees to this meeting included representatives of the MOH, NHIH, NIP, NIRDH, UMP and WHO, and the agenda focused on the elaboration of the drug management guide (see annex 4 for details of participants and the agenda).

RPM Plus joined the meeting and collaborated in defining the contents of the guide.

NEXT STEPS

Immediate Follow-up Activities

1. Complete terms of reference, based on the draft prepared in country, for a contract between the PIU and MSH, to manage the development of a drug management guide for judet level staff.
2. Prepare a budget to accompany this contract.
3. Follow-up with counterparts to schedule the Pharmaceutical Management for MDR-TB course.

Agreement or Understandings with Counterparts

It was agreed with counterparts to give priority to establishing the formal contract between the PUI and MSH regarding the development of the drug management guide.

ANNEX 1. REQUEST FOR COUNTRY CLEARANCE

TO: Gabriella Paleru, USAID/Romania

FROM: Management Sciences for Health (MSH) Rational Pharmaceutical Management Plus (RPM Plus) Program

SUBJECT: Travel of MSH/RPM Plus Senior Program Associate Robert Burn for the period of November 2–11, 2003. RPM Plus Cooperative Agreement No.: HRN-A-00-00-00016-00

COPY: Anthony Boni/ Global HSPR/CTO RPM Plus
Marni Sommer/ Global USAID
Tim Clary/ USAID E&E Bureau
Julia Wallace/ USAID E&E Bureau
Douglas Keene, Director, MSH/RPM Plus
Andrey Zagorskiy, Project Manager for TB, MSH/RPM Plus

1. The RPM Plus Program requests country clearance for MSH/RPM Plus Senior Program Associate Robert Burn to Bucharest, Romania from July 7-17th.
2. Background:

RPM Plus and in-country partners, the Ministry of Health (MOH), National Tuberculosis Control Program (NTP) and the National Health Insurance House (NHIH), are strengthening the drug management information system (DMIS) for the NTP. A steering group, meeting in November, 2003 began to prioritize the identified DMIS needs and plan specific activities to integrate data collection, analysis and use for drug management.

Subsequently in the first half of 2004, the NTP organized a series of one day regional meetings for TB program staff from each judet (county) to review and discuss drug management and reporting. These meetings have been held to develop a common understanding of the issues facing the TB DMIS, to inform about current procedures and to improve ordering practices at the judet level. RPM Plus supported the first of the regional meetings and has worked with the NTP to collect data on drug management and staff training needs through a survey of participants.

In November 2003, RPM Plus and the National Institute for Research and Development in Health (NIRDH) signed an agreement whereby the NIRDH would act as a technical and logistical partner on RPM Plus activities in Romania, to facilitate continued progress or RPM Plus work in between technical assistance visits. Planned activities with the NIRDH include developing the capacity of NIRDH personnel to provide TA on TB drug management issues.

3. Purpose of Proposed Visit:

RPM Plus will work with RPM Plus partner, NIRDH, to finalize the implementation of the next steps of the RPM Plus work plan (training of trainers workshop, DM training for judet level TB staff) and collaborate with the NTP in the development of a DM guide for judet level staff, and monitor implementation of the sub-contract with NIRDH.

4. Scope of work for Robert Burn for this visit is as follows:

- Provide briefing and/or debriefing to the USAID Mission, as requested;
- Prepare a TOT workshop (schedule event, participants list, venue, trainers, etc) to build capacity of NIRDH and NTP staff and local pharmacists to train judet level staff in basic drug management;
- Plan with the NTP, training for TB staff, NHIH representatives and pharmacists from judets in DMIS and DM practice.
- Finalize, under the procurement rules established for the GFATM grant, an agreement for MSH to collaborate on the drafting of a DM Guide with the NTP.
- Further discuss timing and implementation of work plan activities relating to pharmaceutical management for MDR-TB treatment with the NTP, in light of the Romanian application to the Green Light Committee.

5. Anticipated contacts:

USAID/Romania; officials and specialists from the Romanian Ministry of Health and Family; National TB Program; National TB Institute; National Institute for Research and Development in Health; donor agencies and representatives of their programs in the country.

6. Logistics:

Robert Burn will arrive in Bucharest on July 7, 2004. He will depart Romania on July 17, 2004. No Mission assistance is required.

7. Funding:

The in-country work will be paid for with USAID/Romania field support funds.

8. Action:

Please advise Anthony Boni that Robert Burn has received country clearance to travel to Romania as planned. Please reply via e-mail to the attention of Anthony Boni, USAID/G/PHN/HN/HPSR tel (202) 712-4789, fax (202) 216-3702, e-mail address aboni@usaid.gov. Please send carbon copies to Marni Sommer at msommer@usaid.gov, Robert Burn at rburn@msh.org; Andrei Zagorskiy at asagorskiy@msh.org, Douglas Keene at dkeene@msh.org, and Meriel Jimenez at mjimenez@msh.org. Thank you in advance for Mission cooperation.

ANNEX 2. PERSONS MET

Persons met during TDY	
National Tuberculosis Control Programme/ Institute of Pneumology “Marius Nasta”	Professor Paul Stoicescu, General Manager and Director National Tuberculosis Programme Dr. Iuliana Husar, Supervisor National Tuberculosis Program Dr. Cristian Popa, Pneumologist
Dr. Gabriella Paleru	Senior Health Specialist, USAID
National Institute for Research and Development in Health	Dr. Cassandra Butu - Chief of the Training and Consultancy department

ANNEX 3. DRAFT TERMS OF REFERENCE FOR CONSULTANT

Preamble

The National Tuberculosis Program (NTP) with MSH/RPM Plus technical support has been strengthening the drug management component of the national programme. The NTP recently completed a series of five regional workshops (attended by a total of 310 pharmacists, TB physicians and HIIH representatives) on anti-TB drug management and the issues facing the national programme. An analysis of judet orders for TB drugs and pharmacy stock levels was presented which indicated that strengthening drug management capacity would improve the reliability of order quantities and reduce over- or under-stocking.

The participants at the regional meetings were requested by MSH/RPM Plus to complete a questionnaire which provided the basis for an assessment of drug management training needs. The results of the survey show that few staff had received any training in drug management; identified the key aspects of drug management to be addressed by training; and indicated the extent to which participants are currently able to avail themselves of electronic tools and communications.

Planned MSH/RPM Plus program activities include building capacity in drug management training through a Training of Trainers course and subsequent judet level staff training. Romania was awarded a grant by the Global Fund to Fight AIDS, Tuberculosis and Malaria in 2003 for TB and HIV/AIDS activities, which includes, within the drug management component, the preparation of drug management Guide for judet level health facility staff.

The NTP therefore is looking for expertise to prepare a guide to drug management for judet level TB physicians, pharmacists and health insurance house staff (to be known as the *Drug Management Guide*). The consultant will work with Romanian partners of a working group.

Qualification of the Consultant

- International experience in drug management
- Recommendation from WHO as a valuable consultant for this organization
- Previous experience of working with Romanian main stakeholders in anti-TB drug management
- Ability to work in a team with Romanian partners

Detailed scope of work

- Manage production of the *Drug Management Guide*
 - Identify the main steps in designing the anti-TB drug management guidelines for Romania

- Organise the team who will be involved in the development of the guidelines (TB Drug Management Working Group) in collaboration with the NTP
- Outline content of the *Drug Management Guide* with input from the working group
- Identify, with the NTP, individuals from Romania partner organizations who through their knowledge/experience/ideas will contribute to the writing of specific sections of the *Drug Management Guide*
- Provide detailed description of content, section length, and format for sections to be assigned to working group members
- Prepare a bibliography of recent documentation available at the international level to support the content of the *Drug Management Guide*
- Draft sections of the *Drug Management Guide* (not assigned to Romanian partners)
- Review and edit all drafted sections
- Organise translation from Romanian to English of assigned sections for review
- Assemble full draft of document and edit full text to ensure consistency and format
- Present draft to the working group for review and comment (in English), and respond to comments raised, incorporating them into the document as appropriate
- Organise translation into Romania of final text of the Guide

Deliverable

Complete, edited, formatted and printer-ready, final version of the *Drug Management Guide* in MS Word.

Timeframe

- Content agreed and writing assignments of working group finalized: July 31
- Working group members draft assigned sections (and send to consultant): August 31
- Consultant assembles components into first complete draft for review by working group: September 25
- Comments to draft received by consultant: October 15
- Consultant incorporates comments into final document: October 31

ANNEX 4. DRUG MANAGEMENT GUIDE PLANNING MEETING

INVITATION

***Round table on improvement of the drugs management information system for
the National Tuberculosis Control Program***

July 9, 2004

- Crown Plaza -

We are pleased to invite you to participate in a round table on the improvement of the drugs management information system for the National Tuberculosis Control Program organized by the Pneumology Institute Marius Nasta, financed by the Global Fund.

The objectives of this meeting are the following:

- To present a report on the evaluation of the current tb drugs management system realized by the Pneumology Institute Marius Nasta in cooperation with Rational Pharmaceutical Management Plus Program (RPM Plus);
- To discuss the need to elaborate a TB drugs management guide;
- To elaborate future plans in this field.

The meeting agenda is attached.

The round table will take place on July 9th, hour 9,00 – 15,00, in ***Banat Room*** of ***Crown Plaza*** Hotel, B-dul. Poligrafiei.

For any supplementary information and to confirm participation please contact Ioana Novac, phone 337.45.71, ioana.novac@programtb.ro.

Prof. I. P. Stoicescu

NTP Manager

Dr. Cristian Popa

Project coordinator

Agenda de lucru

- 9,00—9,15 Sesiunea de deschidere
Prezentarea participanților
- 9,15—9,30 Trecerea în revistă a programului, obiectivelor și rezultatelor așteptate
- 9,30—10,00 Prezentarea reportului de evaluare a sistemului actual de management al medicamentelor—rezultate ale întrunirilor regionale cu personalul din cadrul rețelei pneumoftiziologie
- 10,00—10,30 Neviole curente de informații și practicile în vigoare de colectare a datelor
- 10,30—11,00 *Pauza de cafea*
- 11,00—12,30 Discutarea necesității elaborării unui ghid de management al medicamentelor antituberculoase
- 12,30—13,30 *Pauze de prânz*
- 13,30—14,30 Planificarea unui sistem coordonat de management al informațiilor referitoare la medicamentele din cadrul Programului Național de Control al Tuberculozei

Lista participanți

Nume și prenume	Instituție
1. Prof. Dr. Ioan Paul Stoicescu	Insitutul de pneumologie „Marius Nasta”
2. Dr. Iuliana Husar	Insitutul de pneumologie „Marius Nasta” – UIP-TB
3. Victor Olsavzsky	Organizația Mondială a Sănătății
4. Robert Burn	MSH
5. Dr. Casandra Butu	INCDS
6. DR. Cristina Jitariu	UMP, Ministerul Sănătății
7. Dr. Emilian Imbri	CNAS
8. Dr. Ioana	DGSPISSS, Ministerul Sănătății
9. Farm. Elena Pascu	UNIFARM
10. Dr. Mădălina Dragoș	Manager județean Maramureș
11. Dr. Anca Macri	Insitutul de pneumologie „Marius Nasta”
12. Dr. Cristina Popa	Insitutul de pneumologie „Marius Nasta” – UIP-TB
13. Dr. Cristian Popa	Insitutul de pneumologie „Marius Nasta” – UIP-TB
14. Dr. Cristi Spiridonescu	Insitutul de pneumologie „Marius Nasta” – UIP-TB
15. Ioana Novac	Insitutul de pneumologie „Marius Nasta” – UIP-TB

BIBLIOGRAPHY

Burn, Robert. 2004. RPM Plus Romania Trip Report: Technical Assistance to the National Tuberculosis Control Program, February 5-11, 2004. Submitted to the U.S. Agency for International Development by the Rational Pharmaceutical Management Plus Program. Arlington, VA: Management Sciences for Health.

Burn, Robert. 2004. RPM Plus Romania Trip Report: Technical Assistance to the National Tuberculosis Control Program, November 2-11, 2003. Submitted to the U.S. Agency for International Development by the Rational Pharmaceutical Management Plus Program. Arlington, VA: Management Sciences for Health.

Burn, Robert and Tom Moore. 2003. *RPM Plus Romania Trip Report Roundtable on the Development of the Drug Management Information System for the National Tuberculosis Control Program in Romania*. Submitted to the U.S. Agency for International Development by the Rational Pharmaceutical Management Plus Program. Arlington, VA: Management Sciences for Health.

Burn, Robert. 2003. RPM Plus Romania Trip Report: *Drug Management Information System for the National Tuberculosis Control Program in Romania*. Submitted to the U.S. Agency for International Development by the Rational Pharmaceutical Management Plus Program. Arlington, VA: Management Sciences for Health.

Makarova, Tatyana, Burn, Robert. 2002. RPM Plus Romania Trip Report: *Assessment of the Drug Management Information System for the National Tuberculosis Control Program in Romania*. Submitted to the U.S. Agency for International Development by the Rational Pharmaceutical Management Plus Program. Arlington, VA: Management Sciences for Health.

Beith, Alexandra and Andrey Zagorskiy. 2002. RPM Plus Romania Trip Report: *Brief Assessment of Procurement for Tuberculosis, HIV/AIDS and Oncology Drugs in Romania*. Submitted to the U.S. Agency for International Development by the Rational Pharmaceutical Management Plus Program. Arlington, VA: Management Sciences for Health.

Management Sciences for Health and the World Health Organization. *Managing Drug Supply: The Selection, procurement, Distribution, and Use of Pharmaceuticals*. Second edition, revised and expanded. W.Hartford, CT: Kumarian Press, 1997

Ministry of Health. National TB Control Program in Romania for 2001-2005. Bucharest, 2001. Order # DB 1597 approved February 15, 2002. Romania.